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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,751

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Elen S. Rosler

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EXAMINER

ZEMAN, MARY K

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,751	Applicant(s) ROSLER ET AL.	
	Examiner Mary K. Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 5 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-3, 5 and 6 are pending. Claims 4 and 7 have been cancelled.

Applicants' arguments and amendments filed 3/26/10 have been entered and carefully considered. Rejections not repeated below have been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5 and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-16 of U.S. Patent No. 6,656,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent according to its effect on cellular signaling pathways involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

Claims 1-3, 5 and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,763,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining activity of a biologically active agent (therapeutic agent) via contacting, measuring, deriving a biomap and comparing limitations. The detailed description of US 6,763,307 states test cells may include endothelial cells. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

Claims 1-3 5 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 18-21 of U.S. Patent No. 7,266,458.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining activity of a biologically active agent via contacting, measuring, deriving a biomap and comparing limitations. The instant application describes transfection (Example 1), inflammation associated pathway (Summary of the Invention), and use of cancer cells (Detailed Description of the Invention). The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 19 28-29, 33-35 of copending Application No. 10/220,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent according to its effect on cellular signaling pathways involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. Paragraph 56 of application 10/220999 states cells used in the assays may be a mixture of cell types. The intended uses for each method are slightly different, however the steps

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of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19-22 of copending Application No. 10/716,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset (produce a biological dataset profile), and comparing limitations. Paragraphs 0052 and 0065 of application 10/220999 states cells used in the assays may be a mixture of cell types and endothelial cells. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8, and 13-14 of copending Application No. 10/856,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-34, 38-43, 46-49 of copending Application No. 11/929790. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-29 of copending

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Application No. 11/929841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/848596. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The instant application describes transfection (Example 1), inflammation associated pathway (Summary of the Invention), and use of cancer cells (Detailed Description of the Invention). The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9 of copending Application No. 10/554043. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 5 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 9 11-16 of copending Application No. 10/570081. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The intended uses for each method are slightly different, however the steps of the method are essentially the same. An agent is applied to a system consisting of one of a list of systems, and data is collected, then compared.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

Claims 1-3 5 6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (US 6,656,695). The claims have been significantly amended, thus the rejection is expanded to address new limitations.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Berg et al disclose method of characterization of agents using the Biomap system of the instant specification. Asthma and Atopy context systems are specifically described at col 32-35. Profiles of the asthma/atopy context are derived in the absence of, and in the presence of a candidate agent, and various parameters are compared. Various types of agents are disclosed including biological and chemical. Bronchial cell, mast cell and Th2 T cells are disclosed. As such, the rejected claims are anticipated.

Berg et al. disclose a method for determining the activity of a biologically active agent according to its effect on cellular signaling pathways (abstract; claim 1), the method comprising: measuring at least two (or three) different cellular parameter readouts in primary human cells in a first cell culture system comprising peripheral blood mononuclear cells and endothelial cells or an Asthma/Atopy context in the presence of combinations of IL-1, IL-2, IL-3, TNF, IFN, IL-4, histamine, superantigen (Sag) or LPS in the presence of a test agent as well as in said system lacking the test agent, measuring readouts in a second cell culture system comprising endothelial cells activated in multiple signaling pathways by IL-beta, TNF-alpha, and IFN-gamma in presence and absence of test agent (abstract; claims 1-5; col. 11, third paragraph to col. 13, first two paragraphs, col. 15, last paragraph to col. 17, first paragraph; Example 19);

recording changes in at least two different cellular parameter readouts in presence of said agent (claim 1; col. 9-11);

deriving a first and second datasets from said changes in parameter readouts wherein said dataset comprises data normalized to control data on the same said primary human cells under control conditions lacking said biologically active agent, and wherein output parameters have a robust modulation in response to one or more factors or agents of the system (col. 9, third paragraph to col. 10, last paragraph);

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comparing said first and second datasets to a reference dataset to determine the presence of variation, wherein the presence of variation indicates a difference in the effect of the test biologically active agent on a cellular signaling pathway (claim 1; col. 10, last paragraph to col. 12, last paragraph), as stated in instant claim 1.

Berg et al. disclose at least 2 parameters and not more than ten parameters are measured (claim 2), as stated in instant claim 1-3 4 5.

Thus, Berg et al. anticipate the instant invention.

Applicant argues that Berg et al. do not teach assaying the response of multiple cell culture systems to a test agent and comparing these responses. This statement is found unpersuasive as Berg et al. teach creating many biomap dataset combinations with and without a test agent and performing comparisons (abstract; claims 1-5; col. 9, third paragraph to col. 13, first two paragraphs, col. 15, last paragraph to col. 17, first paragraph; Example 19). The claims require the use of only one of the listed systems, and not all of them.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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/Mary K Zeman/

Primary Examiner, Art Unit 1631